

REMARKS / ARGUMENTS

In the above-identified Office Action the Examiner has rejected claims 1-3, 13 and 17-22 as unpatentable over Spielberg in view of Sobel, Gillis and Gennaro. The Examiner has stated that the claimed ranges defined concentrations of each agent which fall slightly below the amounts taught as effective by Sobel and Gillis and that with the general conditions of the claim disclosed in the prior art it is, therefore, not inventive to discover the optimum ranges by routine experimentation. The Examiner has also stated that there is no evidence of the criticality of these amounts and thus the differences from the prior art is not enough to render the claims patentable over the prior art. In a situation such as this, the MPEP 2144.05 states that the Applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range, citing *In re Woodruff*, 919 FED 2nd 1575; 16 USPQ 2nd 1934 (Fed Cir 1990). Accordingly, Applicant hereby submits a statement by one of the inventors in addition to that previously submitted to the effect that the study described therein supports the unexpected and surprising conclusion that the inventive dosage of a single tablet having from about 10 to less than 150 mg fluconazole and from about 1000 to less than 2000 mg tinadazole for use as a unit dose is just as effective as a standard dosage with a lower incidence of reported side effects (see paragraph 24 of the statement by Raul E. Garcia Salgado Lopez). This statement describes a study undertaken concerning the dosages set forth above and analyzes that study with regard to statistical determination of the validity of the results.

As stated in a previous response, lowering dosage of medicaments is counterintuitive, if one wishes to cure a specific disease. Further, lowering the dosage is not recommended because, as a person skilled in the art would know, it could affect

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the treatment by possibly creating resistant microorganisms. Despite such knowledge, Applicant lowered the dosage and still achieved a surprisingly effective treatment of the disease. As such, Applicant believes the claims to be patentable.

Claims 1, 13, 17, 19 and 21 have been rejected as unpatentable over Spielberg in view of Sobel, Wallins, and Remington's. Applicant disagrees with the Examiner's assertion in this regard noting that the Examiner has recognized that the concentrations do fall outside the ranges taught by the prior art and, thus, with the evidence of criticality as described above, Applicant believes that the claims are patentable and overcomes what the Examiner states to be the *prima facie* obviousness present here.

Claims 2, 3, 18, 20 and 22 been rejected as unpatentable over Spielberg in view of Sobel, Videau and Remington's. Applicant refers to the above-described statement by Raul E. Garcia Salgado Lopez and also to the previously submitted declaration by Luisa Hernandez Ramirez in which both state that the claims state critical parameters in the administration of Applicant's invention and, accordingly, because of this criticality, Applicant believes that the claimed range achieves unexpected results relative to the prior art range.

Claims 1,13, 17, 19 and 21 have been rejected as unpatentable over Spielberg in view of Sobel, Wallins, and Remington's and in view of the two statements by two of the inventors herein and described above. Applicant believes that it has sufficient evidence showing that the claim range achieves unexpected results relative to the prior art range cited and, accordingly, the subject claims should be patentable in view of such prior art.

Claims 2, 3, 18, 20 and 22 have been rejected as unpatentable over Spielberg in view of Sobel, Videau and Remington's. As above, Applicant believes that the declarations and statements filed by the two inventors are sufficient evidence to prove

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that the claimed range achieves unexpected results and is critical relative to the prior art range and, accordingly, such claims should be patentable.

Claims 6 and 16 stand rejected as unpatentable over Spielberg in view of Sobel, Gillis and Remington's. For the reasons stated above, Applicant believes that the claims should be patentable. Claim 16 stands rejected as unpatentable over Spielberg in view of Sobel, Wallins and Remington's taken in view of USP 5,660,860. For the reasons stated above, i.e., the submission of evidence including a declaration and the enclosed statement in support of the criticality of the ranges, Applicant believes that the claims are allowable. Claim 6 stands rejected as unpatentable over Speilberg in view of Sobel, Videau Remington's and taken in view of USP 5,660,860. Applicant restates its contention that the claim is allowable in view of the submission of evidence including a statement and a declaration that the ranges are critical as set forth in more detail above and, therefore, the claims should be allowable.

Applicant hereby requests reconsideration and reexamination thereof.

No further fee or petition is believed to be necessary. However, should any further fee be needed, please charge our Deposit Account No. 23-0920, and deem this paper to be the required petition.

With the above amendments and remarks, this application is considered ready for allowance and applicant earnestly solicits an early notice of same. Should the Examiner be of the opinion that a telephone conference would expedite prosecution of the subject application, he is respectfully requested to call the undersigned at the below listed number.

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Respectfully submitted,



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